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UNDER 37 CFR 1.8(a)

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31 January 2006
HUESCHEN AND SAGE

Michael M. C. S.
Dated: 31 January 2006

SERVIER 408

Applicant : Lucile VAYSSE-LUDOT, Jean-Pierre LECOUE, and Pascal LANGLOIS

Serial No. : 10/669,738

Filed : September 24, 2003

Title : Process for the industrial synthesis of the methyl diester of 5-amino-3-carboxy-methyl-4-cyano-2-thiophenecarboxylic acid, and application to the synthesis of bivalent salts of ranelic acid and their hydrates

Art Unit : 1626

Examiner : Golam M. SHAMEEM, Esq.

Honorable Commissioner for Patents
PO Box 1450
Alexandria, VA 22313

COMMUNICATION COVERING TRANSMITTAL OF INFORMATION DISCLOSURE

STATEMENT UNDER 37 CFR §§ 1.97 AND 1.98

Sir:

Herewith, in accord with the foregoing regulations, please find an Information Disclosure Statement which, it is respectfully submitted, should materially advance and accelerate the prosecution of the above-identified application. It is respectfully requested that the information be expressly considered during the prosecution of

this application and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

As will be noted, this Information Disclosure Statement calls a number of prior art references, which might be considered relevant, to the attention of the Examiner. The fact that these are in fact "Prior Art" is, however, not admitted.

The Applicants respectfully submit that EP 0 415 850, which is already of record in the instant application, discloses a process for preparing strontium ranelate, starting from the tetraethyl ester of N,N-di(carboxymethyl)amino-2-cyano-3-carboxymethyl-4-carboxy-5-thiophene, and refers to the Wierzbicki, et al. reference for the preparation of the tetraethyl ester.

Neither EP 0 415 850 nor Wierzbicki, et al. suggest the very specific operating conditions of the instantly claimed process, i.e., preliminary reaction of dimethyl 3-oxoglutarate with malononitrile and morpholine to yield the intermediate compound of formula (VII), followed by the addition of sulfur and heating of the mixture at reflux in ethanol. Moreover, neither reference suggests that these specific conditions would allow methyl 5-amino-4-cyano-3-(2-methoxy-2-oxoethyl)-2-thiophenecarboxylate to be obtained in a yield greater than 70%. Therefore, the Applicants respectfully submit that the instantly claimed process is not anticipated nor rendered obvious by the disclosure of EP 0 415 850 and Wierzbicki, et al.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR § 1.98 and the Examiner is respectfully requested to consider the listed references.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

By: 
G. PATRICK SAGE

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Enclosure: Form PTO-1449 and Accompanying References and Postal Card
Receipt.

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**THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER
OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION,
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PTO-1449 LIST OF PRIOR ART CITED BY APPLICANT SHEET 1 OF 1	ATTY. DOCKET NO. SERVIER 408	SERIAL NO. 10/669,738
	APPLICANT L. VAYSSE-LUDOT, J-P. LECOUE, P. LANGLOIS	
	FILING DATE September 24, 2003	GROUP 1626



U.S. PATENT DOCUMENTS

Examiner Initial	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
					YES	NO
EP 0415850	06 March 1991	EPO				

OTHER PRIOR ART

	French Search Report for French Application No. 02.11764, April 1, 2003.
	International Preliminary Examination Report for International No. PCT/FR2003/002776, December 3, 2004.
	WIERZBICKI, et al., <i>Bull. Chim. Soc. Fr.</i> , 1975, 7-8, 1786-1792.
EXAMINER	DATE CONSIDERED
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	